

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1, 3, 4, and 12-41 are pending and directed to an isolated antigen (claims 1, 3, 4, and 36-41), a ligand that recognizes the antigen (claims 12-19 and 33-35), a composition comprising the ligand (claims 20-30), and a method for treating a cancer disease (claims 31 and 32).

Claims 36-41 are labeled as withdrawn in view of the Office Action. Applicants note that claims 36-41 have been amended to refer to the antigen of claim 3. Accordingly, claims 36-41 are directed to the elected subject matter of Group I (i.e., a tumor surfaced exposed antigen). Applicants, therefore, request consideration of claims 36-41.

Claims 12-35 are labeled as withdrawn in response to the earlier restriction requirement. Applicants request the rejoinder and examination of claims 12-35 at such time as a pending claim is indicated allowable inasmuch as claims 12-35 depend from elected claim 1 and contain similar limitations to those recited in the other pending claims under examination.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claims 1 and 31-33 have been amended to recite that the cultured cancer cell is from gastric cancer, breast cancer, colon cancer, or esophageal cancer as supported by the specification at, for example, page 6, lines 1-4; page 11, lines 12-18; and Example 4.

Additionally, claims 36-41 have been amended to replace “method” with “antigen” since the claims depend from claim 3 or 4, which claims are directed to an “antigen.”

No new matter has been added by way of these amendments to the claims.

Correction of Inventor's Name

The first name of the first inventor (Yoko Hirakawa) was misspelled on the Application Data Sheet filed on April 4, 2005, and the Combined Declaration and Power of Attorney filed on May 17, 2005, although the first inventor's signature is correctly set forth on the Combined Declaration and Power of Attorney. Applicants hereby correct the spelling of the first name of the first inventor by submitting herewith a Supplemental Application Data Sheet, with the understanding that the U.S. Patent and Trademark Office will provide an updated Filing Receipt to reflect the proper spelling of the first name of the first inventor in due course.

Summary of the Office Action

The Office rejects claims 1, 3, and 4 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

The Office rejects claims 1, 3, and 4 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description.

Reconsideration of these rejections is hereby requested.

Discussion of the Rejection Under Section 112, Second Paragraph

The Office contends that it is not clear from the specification where the formation of the tumor is occurring and where the cell should be positioned in relation to this formation. The Office requires clarification about whether (a) only cells along the edge of a growing tumor mass are included, or (b) every cell in the solid tumor mass would express part of the antigen on its cell surface.

Claim 1, as amended, recites that the antigen consists of a part that is exposed on a surface of a cell of a solid tumor.

Consistent with the description in the specification, Applicants describe an experiment in the Declaration Under 37 C.F.R. § 1.132 (submitted herewith) that demonstrates that GAH reacts to all populations of the tumor cells (Fig. A). The results in Fig. A correspond to the raw data for Fig. 1 of the application. The data support that every

cell in the solid tumor mass expresses part of the non-muscle myosin heavy chain A (nmMHC-A) antigen (SEQ ID NO: 17) on its cell surface.

Accordingly, one of ordinary skill in the art would understand the relationship between the cell and the tumor and that all the cells of the solid tumor mass express part of the antigen on their cell surface. Therefore, Applicants request that the indefiniteness rejection be withdrawn.

Discussion of the Rejection Under Section 112, First Paragraph

The Office contends that the claims encompass *any* kind of cultured cancer cell and the solid tumor from which it is formed, but that the specification only supports certain cell lines.

The claims, as amended, recite that the cultured cancer cell is from breast cancer, colon cancer, esophageal cancer, or gastric cancer, which is described in the specification at, for example, page 6, lines 1-4, and page 11, lines 12-18. In particular, Examples 1-5 describe numerous cell lines derived from these cancers.

Furthermore, consistent with the description in the application, Applicants describe experiments in the Declaration Under 37 C.F.R. § 1.132 that demonstrate the reactivity of the GAH antibody and/or the anti-nmMHCA antibody with cells derived from colon cancer (Fig. B), esophageal cancer (Fig. B), and breast cancer (Fig. C). To perform these experiments, Applicants used the method described at page 21, line 4, through page 22, line 4, of the application.

Thus, the specification of the application contains adequate written description of cultured cancer cells from several cancers, including breast cancer, colon cancer, esophageal cancer, and gastric cancer.

The Office also contends that (a) the specification does not demonstrate that an antigen comprising only residues 600-1,960 of SEQ ID NO: 17 would be the part of the antigen that is exposed on the cell surface of the cultured cell and (b) the recited domain (residues 600-1,960 of SEQ ID NO: 17) would not be able to associate with the cell

membrane. The Examiner cites to Wei et al. as evidence that a truncated nmMHC-A protein does not associate with the cell membrane.

The claims, as amended, recite an isolated antigen that (1) consists of a part which is exposed on a surface of a cell of a certain solid tumor and (2) comprises residues 600-1,960 of SEQ ID NO: 17. *Both* features (1) *and* (2) must be satisfied for the antigen.

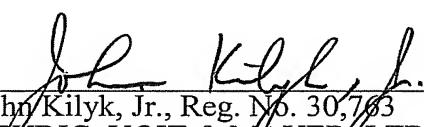
Wei et al. discloses that a truncated nmMHCA ($\Delta N592$) binds to an endogenous myosin. However, this disclosure does not preclude the possibility that a part of the truncated nmMHCA is expressed on the surface of cells. Accordingly, Wei et al. does not contradict the present invention.

For the foregoing reasons, the specification adequately describes the pending claims and the written description rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: November 30, 2007